Welch Allyn

K 121013

JUL 2 6 2012

# 510(k) Summary

[As described in 21 CFR 807.92]

**Submitted by:**

Welch Allyn Inc.
4341 State Street Road
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**Contact Person:**

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Director of Regulatory Affairs
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**Date Prepared:**

June 26, 2012

**Trade Name:**

Welch Allyn Connex® Vital Signs Monitor 6000 Series

**Common Name:**

Monitor, Physiological, Patient (without Arrhythmia Detection or Alarms)

**Classification Reference:**

Class II, 870.2300, Cardiovascular Monitoring Devices
Product Code - MWI

**Predicate Devices:**

**Welch Allyn Connex® Vital Signs Monitor – VSM 6000 Series (with Applications Framework)**
Vital Signs Monitor, CVSM 6000 Series, CVSM
Welch Allyn, Inc.
510(k) Number K112687

**Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and Accessories**
Pulse Oximeter and Sensor
Masimo Corporation
510(k) Number K100428

**Oridion Capnostream20® with MicromediCO2 Module**
Carbon Dioxide Gas Analyzer
Oridion Capnography, Inc.
510(k) Number K094012

**Welch Allyn VSM (vital signs monitor), Propaq LT**
Physiological Patient Monitor
Welch Allyn, Inc.
510(k) Number K033378

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## Description of the Device:

The Welch Allyn Connex® Vital Signs Monitor 6000 Series is designed to provide a scalable, modular system of components that can be configured to address the needs for vital signs spot check and continuous monitoring.

The Welch Allyn Connex® Vital Signs Monitor 6000 Series monitor is intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. Patient monitors equiped with Masimo Rainbow SET® pulse Co-Oximeter modules are also capable of total hemoglobin measurements (SpHb, SpHbv) and acoustic respiration rate (RRa). Patient monitors equiped with Oridion capnography are also capable of carbon dioxide ($CO_2$), respiration rate (RR) and calculation of Integrated Pulmonary Index (IPI). The CVSM can also display and transfer patient data that is electronically or manually entered from external and accessory devices, e.g., weight and height data, barcode scanner, IR temperature, and other patient or facility information. Data can be transferred electronically via USB, wired Ethernet, or wireless communications. Ethernet and wireless are intended for communication of vital signs parameters, patient data, and alarms (including continuous and episodic parameters and alarms) to secondary remote viewing and alarming systems. The Welch Allyn Application Framework (Framework) – has been included as a separate subsystem. The Framework is general purpose software that allows medical device and non-medical device software applications to run on the Framework independently of and isolated from the CVSM's vital signs monitoring functionality.

The monitor has an enclosure constructed of engineered plastics with internal steel members for strengthening. A silicone light bar is prominent in a carry handle on the top of the device and illuminates for different alarm conditions. A power button is located on the side of the device. A touch screen display is prominent on the front of the device and provides the primary interface for the user to interact with the device. Internal and external communications are primarily by USB. External host USB connections for accessories are tool accessible. A USB connection for data transfer is on the side of the device, as is a connection to an internal relay for use with nurse call systems. The device contains an internal AC power supply for operating the device and charging the internal Lithium Ion battery.

The monitor can be configured for use in different workflows including desktop, affixed to a mobile stand, or on a wall mount.

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**Indications for Use:**

The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients for:

- noninvasive blood pressure,
- pulse rate,
- noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and
- body temperature in normal and axillary modes.

The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments. Monitoring can be accomplished on the VSM 6000 series bedside monitor itself and the VSM 6000 series bedside monitor also can transmit data continuously for secondary remote viewing and alarming (e.g., at a central station). Secondary remote viewing and alarming features are intended to supplement and not replace patient bedside monitoring.

The optional Masimo Rainbow SET® Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, total hemoglobin concentration (SpHb), and/or respiration rate (RRa). The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

The optional Oridion module and accessories are intended for the continuous non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric and adult patients in hospitals and hospital type facilities.

The optional Oridion module also provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

Optional compatible weight scales (e.g., Health o meter®) can be used for height, weight, and BMI input.

WelchAllyn

The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework ("Framework"). The Framework is general purpose software that allows medical device and non-medical device software applications to be run on the CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting.

This product is available for sale only upon the order of a physician or licensed health care professional.

**Technological Characteristics:**

The subject device has the same technological characteristics and indications for use as the predicate devices; minor modifications and additions to software and hardware were made to the CVSM to enable acquisition and display of acoustic respiration rate (RRa) utilizing the existing Masimo Rainbow SET® module and also the acquisition and display of carbon dioxide ($CO_2$), respiration rate (RR), and a calculated integrated pulmonary index (IPI) utilizing the Oridion capnography module. The Welch Allyn Application Framework (Framework) – has been included as a separate subsystem. The Framework is general purpose software that allows medical device and non-medical device software applications to run on the Framework independently of and isolated from the CVSM's vital signs monitoring functionality.

**Non-Clinical Tests:**

Verification and validation were conducted to ensure expected performance of the CVSM 6000 Series with enabled Masimo Rainbow SET® and the Oridion capnography module.

The Connex® Vital Signs Monitor 6000 Series was tested to evaluate its safety and effectiveness based on the following standards:

- IEC 60601-1:Ed. 2: 1988 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (with A1:1991 +A2:1995)
- IEC 60601-1-2: Ed. 3: 2007 – Medical electrical equipment – Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Test
- IEC 60601-1-4: Consolidated Ed. 1.1: 2000 – Medical electrical equipment – Part 1-4: General requirement for safety: Collateral standard: Programmable electrical medical systems
- IEC 60601-1-8: Ed. 1: 2003 – Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: Alarm systems –

Requirements, tests and guidances – General requirements and guidelines for alarm systems in medical equipment (with A1:2006)

- IEC 60601-2-30: Ed. 2: 1999 – Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
- IEC 60601-2-49: Ed. 1: 2001 – Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
- ISO 9919: Ed. 2: 2005 – Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
- ISO 14971: Ed. 2: 2007 – Medical devices – Application of risk management to medical devices
- ISO 21647: Ed 1: 2004 – Medical electrical equipment, Part 2: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- IEC 62304: Ed. 1: 2006 – Medical Device Software - Software Life-Cycle Processes

**Clinical Performance Data:**

No clinical studies were utilized for the purpose of obtaining safety or effectiveness data.

**Conclusion:**

Based on the information presented in this 510(k) premarket notification, Welch Allyn's Connex® Vital Signs Monitor 6000 Series is considered substantially equivalent (as safe, as effective and performs as well as) the currently marketed devices cited in this submission.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

Welch Allyn, Inc.
c/o Mr. Kevin Crossen
Director, Regulatory Affairs
4341 State Street Road
Skaneateles Falls, NY 13153

Re: K121013
Trade Name: Connex Vital Signs Monitor 6000 Series
Regulation Number: 21 CFR 878.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: June 26, 2012
Received: June 29, 2012

Dear Mr. Crossen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

K121013

510(k) Number (if known): K121013

Device Name: Welch Allyn Connex® Vital Signs Monitor 6000 Series

Indications for Use:

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Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH; Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121013

K121013

## Indications for Use (continued)

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